Indications for the clinical use of unattended portable recording for the diagnosis of sleep-related breathing disorders.

CLINICAL PRACTICE REVIEW COMMITTEE
AMERICAN SLEEP DISORDERS ASSOCIATION

The ASDA often receives requests for medical opinion on procedures and practices employed by our members. In most instances, the ASDA has no official practice guideline or standard on the matter and is unable to develop such a standard due to a paucity of evidence in the existing literature. However, the importance of rendering an opinion is recognized.

Under the Association's current committee structure, there is no standing committee charged with this responsibility. In response to this, the ASDA Board of Directors, at its November meeting, voted to appoint a Clinical Practice Review Committee, whose purpose will be to evaluate the quality and efficiency of physician medical performance in the sleep center setting and respond to concerns of physicians, patients, and third-party payers as well as other special issues referred by the Board.

The position report on portable recording that follows this introduction is an example of the kind of issue which the newly established committee might address in the future. It is anticipated that the Clinical Practice Review Committee will be fully operational within the next three months.

The following report has been accepted by the Board of Directors of the American Sleep Disorders Association as a position paper.

Executive Summary

Based on a review of the available literature including existing published standards of practice and consensus opinion, unattended portable recording may be effective for the diagnosis of severe sleep-related breathing disorders (SRBD) when used by a qualified sleep specialist as part of a comprehensive sleep consultation. Portable recordings used as an isolated procedure by unqualified clinicians may result in improper care and higher health care costs due to its application for inappropriate diagnostic indications.

Portable Recording—Overview

The development of portable recording devices has the potential to improve access and lower the cost of care for patients with sleep disorders. However, there are no studies to date that convincingly demonstrate that these devices are cost-effective in controlling overall health care costs. Indeed, the increase in access may result in a large rise in overall SRBD-related health care costs related to inappropriate use. Thus, one of the major challenges to those who advocate use of portable recording devices is developing guidelines and ensuring appropriate utilization.

The increasing awareness of sleep disorders in the medically and psychiatrically ill, in children, and the elderly, has resulted in the referral for sleep studies of more medically complex patients. These patients may not be adequately served if the focus of evaluation is solely on the diagnosis of SRBD using portable recorders. Furthermore, there is increasing recognition that there are many patients with subtle but highly symptomatic forms of SRBD such as Upper Airway Resistance Syndrome. These entities require more sophisticated data acquisition techniques and thus use of some forms of portable recording technology may be inadequate or misleading.

These issues highlight the necessity that portable recording technology must be part of a continuum of care. Individuals initially identified as having a disorder using these techniques should have access to a full spectrum of clinical and diagnostic services if clinically indicated. Therefore, it is critically important that practitioners who use portable recording technologies are knowledgeable concerning the broad field of sleep medicine, recognize the limitations of the portable recording techniques being used and have access to standard laboratory polysomnography.

This paper clarifies and makes recommendations for 1) the indications for the use of portable recording devices in the evaluation of SRBD, 2) The clinical expertise required of clinicians interpreting data obtained from these devices and 3) the responsibility for providing the continuum of care for the patient. These recommendations are not intended to replace previous standards of practice published by the American Sleep Disorders Association. Rather, they complement them by providing guidelines on how these techniques should be integrated in the continuum of care of patients with sleep disorders.

Portable Recording Standards

The American Sleep Disorders Association has published standards for the use of unattended portable comprehensive polysomnography (1), unattended limited polysomnography (1) and attended limited polysomnography (2). As shown in the Table below, the ASDA has proposed that four levels be used to classify the complexity of recording technology

Table 1—Types of studies for sleep apnea evaluation (6-hour overnight recording minimum)

A. Level I: Standard polysomnography
Minimal requirements include recording of electroencephalogram (EEG), electrooculagram (EOG), chin electromyogram (EMG), electrocardiogram (ECG), airflow, respiratory effort and oxygen saturation. Body position must be documented or objectively measured. Trained personnel must be in constant attendance and able to intervene. Leg movement recording (EMG or motion sensor) is desirable but optional.

B. Level II: Comprehensive portable polysomnography
Same as for Level I except heart rate instead of ECG is acceptable, and having trained personnel present and able to intervene is not required for all studies.

C. Level III: Modified portable sleep-apnea testing
Minimum requirements include recording of ventilation (at least two channels of respiratory movement, or respiratory movement and airflow), ECG or heart rate and oxygen saturation. Personnel are needed for preparation, but the ability to intervene is not required for all studies.

D. Level IV: Continuous (single or dual) bioparameter recording
Only one or two physiologic variables need be recorded. The ability to intervene is not required.

used for the diagnosis of SRBD (1). According to these guidelines (2), a Level 3 (cardiorespiratory) sleep study attended by a technician is acceptable to diagnose SRBD in patients with a high prestudy probability of having SRBD (at least 70%) according to validated questionnaire(s) and physical examination (3). According to these same guidelines (1,2), unattended Level 2 and 3 studies can be used 1) in cases when patients have severe symptoms (defined as several of the following: loud snoring, observed apneas, nocturnal choking, daytime sleepiness, hypertension and moderate to severe obesity) and attended standard polysomnography is not readily available or the patient cannot be studied in the sleep laboratory; or 2) for follow-up after diagnosis has been made with attended standard polysomnography and therapy was initiated. This does not imply that patients with suspected SRBD may be diagnosed and treated on the basis of questionnaires and portable recordings by physicians without sleep medicine expertise—on the contrary, portable recordings, due to their limitations and the increasing complexity of the patient population, require the clinical skill of physicians qualified to interpret such recordings (vide infra). A negative portable study requires follow-up with attended standard polysomnography because the sensitivity of a Level 3 study is inadequate to detect all forms of SRBD (3). According to ASDA guidelines (1,2), Level 4 studies are unacceptable for diagnosis or screening for OSA. A recent retrospective cohort study also supports this conclusion (4).

Based on the most recent analysis of the literature (2), a minimum of airflow, respiratory effort, arterial oxygen saturation, and ECG or heart rate are required to provide an attended cardiorespiratory study that is sensitive and specific enough to be useful to diagnose SRBD with an apnea-hypopnea index (AHI)> 10 events per hour. In addition to the four channels already described, it is recommended that an unattended cardiorespiratory study requires a continuous measure of position.

Sleep laboratories may choose from the available validated questionnaires cited in reference 3, section 4.3.2.2.

It is essential that patients be informed of the limitations of such cardiorespiratory studies including their inability to diagnose the upper airway resistance syndrome (UARS) (2,3). The UARS consists of symptoms of excessive daytime sleepiness with EEG determined respiratory arousals >10 per hour in a patient with an AHI <10 per hour (2,3)

Qualifications of the Interpreting Clinician

The diagnostic use of portable devices for assessing sleep disorders is a highly sophisticated field. For this reason, individuals who deliver such services should be qualified to do so and understand their limitations. Therefore, the individual interpreting portable recordings should have knowledge and skills related to the diagnosis and treatment of SRBD and the ability to recognize other sleep disorders when such studies are ordered primarily for the evaluation of SRBD. When studies are ordered to assist in the diagnosis of a broad range of sleep disorders, the interpreting practitioner should have knowledge and skills of the entire field of sleep medicine. Suggested qualifications for such individuals include diplomates of the American Board of Sleep Medicine (1), individuals who have completed a one-year fellowship in sleep medicine (1), and other physicians who have received additional training in sleep medicine or SRBD. Furthermore, individuals interpreting portable recordings also must be readily able to interact with a sleep disorders center so that any additional diagnostic testing, treatment, and long-term follow-up can be easily provided. Interpretations rendered by individuals who have little or no personal training and experience in the comprehensive treatment of patients with sleep disorders or SRBD are to be discouraged.

Conflicts of Interest and Portable Recording

Diagnostic and therapeutic decisions should not be influenced by actual or potential conflicts of interest. The American Medical Association's code of ethics states, "(A) Physician should not be influenced in the prescribing of drugs, devices, or appliances by a direct or indirect financial interest in a pharmaceutical firm or other supplier." This principle applies to the provision of CPAP/bi-level positive airway pressure equipment to a patient by a facility or provider who has performed a portable sleep diagnostic recording, as well as for standard polysomnography.

Nevertheless, it is recognized that in order to provide timely, supportive and cost-effective service to the patient, qualified sleep centers or sleep-related breathing disorders laboratories may be in the most knowledgeable and effective position to provide CPAP/bi-level positive airway pressure equipment. Therefore, sleep center or laboratories may choose to provide CPAP/bi-level positive airway pressure equipment and services after legal consultation regarding their specific circumstances. In all these and similar situations, disclosure of financial interest is required with clear documentation that the patient was informed of their right to choose an alternative provider.

Integration of Portable Recording in the Contunuum of Care

Responsibility for Follow-up Care in Home Testing Programs

Sleep studies, unlike many other diagnostic tests, cannot be properly interpreted without detailed knowledge of the patient's relevant medical history and expert knowledge of sleep medicine, so that home portable recording programs must not be viewed as just a laboratory test procedure, but as part of a consultative service. All home-testing programs must have a qualified physician responsible for deciding and directing treatment, and establishing a care plan. A formal, efficient, and effective system must be in place that integrates the home-testing diagnostics with the treatment and follow-up plans for each patient regardless of the recording technology utilized. Such a program must be able to provide or have available the full range of diagnostic and treatment modalities related to sleep medicine.

Relationship of Home Testing Programs to Facility-based Sleep Disorders Centers and Laboratories

Any patient initially tested using unattended portable recording who does not have a satisfactory diagnosis and treatment of their sleep disorder must have easy and automatic access to a comprehensive sleep consultation and additional diagnostic testing. The central role of the sleep specialist in this process cannot be overemphasized. Therefore, a home-testing program dedicated to quality care will either originate from or have some formal affiliation with a comprehensive sleep disorders center or sleep-related breathing disorder laboratory so that the continuum of patient care will be ensured.

References

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